UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,663	02/27/2004	Rainer Gruening	136-36	3625

23869 7590 01/13/2009

HOFFMANN & BARON, LLP
6900 JERICHO TURNPIKE
SYOSSET, NY 11791

EXAMINER
CHONG, YONG SOO

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
01/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/788,663	GRUENING ET AL.	
	Examiner	Art Unit	
	YONG S. CHONG	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-32 and 34-53* is/are pending in the application.

4a) Of the above claim(s) *37,39 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-32, 34-36, 38, 41-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 10/6/08. Claim(s) 1-23, 33 have been cancelled. Claim(s) 53 has been added. Claim(s) 24-32, 34-53 are pending. Claim(s) 24 has been amended. Claim(s) 37, 39-40 have been withdrawn. Claim(s) 24-32, 34-36, 38, 41-53 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejections of the last Office Action are maintained for reasons of record and modified below as a result of Applicant's amendments to the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-32, 34-36, 38, 41-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 11/416,060. Although the conflicting claims

are not identical, they are not patentably distinct from each other because a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, spermicide, and glutaraldehyde is disclosed for the purpose of inhibiting the intrusion of micro-organisms into a body cavity in the preamble.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's request to file a terminal disclaimer once the instant application is allowed, is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 24-32, 34-36, 38, 41-50, 53 are rejected under 35 U.S.C. 103(a) as being obvious over Beckman et al. (US Patent Application 2002/0015697 A1).

The instant claims are directed to a method of inhibiting the intrusion of microorganisms into a body cavity of a mammal comprising applying into the body cavity a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, and glutaraldehyde.

Beckman et al. teach methods, compositions, and kits for reducing a microbial population on a surface (abstract), such as the epidermal skin, mucosal surface, a wound, an abrasion, a burn, or a damaged region of tissue (section 0009). Other medical applications include the skin of a patient, teat of a dairy cow, oral cavity, vaginal cavity, and other living tissues of human beings (section 0078). The composition comprises transition metals prepared in water (section 0043), iodine, glutaraldehyde (section 0049), polyurethanes (section 0051), chitosan (section 0052), polyvinylpyrrolidone (section 0145), parabens (section 0149), water, alcohol, and dyes (section 0155). The antimicrobial compositions can be applied with a sponge, a mop, a cloth, or any other of a variety of techniques known to one of skill in the art of disinfection (section 0055). The methods of the present invention can employ other compounds or procedures known to those skilled in the art which result in a viscous gel to ensure adequate exposure of the disinfectant solutions to the treated surface. The gel, by adhering to the surface, provides a longer exposure time than would be achieved with a simple liquid (section 0058). Furthermore, a range of concentrations of

free iron can be employed in the methods for reducing a microbial population within an aqueous solution. For example, the free iron can be provided at a concentration as low as between about 0.1 μM to about 1 M free iron. Higher concentration of stress inducer may also be of particular use in some embodiments (sections 0071 and 0092). Example 3 discloses the use of range of concentrations for a stress inducer (Figure 5). Another example discloses 100 mM iron citrate and between 0.01% to 15% chitosan. Optionally, the composition comprises between about 0.01% to 10%, preferably about 1% chitosan (section 0158).

Generally, mere optimization of ranges will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimal or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." *In re Peterson*, 315 F. 3d at 1330, 65 USPQ 2d at 1382; It has been held that it is within the skills in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 1980) MPEP 2114.04

It is obvious for one of ordinary skill in the art to use O-carboxymethyl chitosan and ethyl or isopropyl alcohol since the genus chitosan and alcohols were disclosed in the prior art. It is also obvious for one of ordinary skill in the art to use hydrogels since

the genus, gels, have been taught by the prior art. Examiner notes that this is a typical genus/species situation. Once a *prima facie* case of obviousness is established, the burden is shifted to the Applicant for objective evidence for nonobviousness. See MPEP 2144.08.

It is noted that limitation in claims 24 and 53 reciting "wherein the hydrogel is capable of reducing or eliminating the level of micro-organisms without the inclusion of antibiotics or antimicrobials" is given little patentable weight because it is merely considered a property of the composition. There is no recitation in the claims that precludes the inclusion of antibiotics or antimicrobials in the composition.

However, Beckman et al. fail to disclose a single example of a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, and glutaraldehyde.

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to formulate a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, and glutaraldehyde for the method of inhibiting the intrusion of microorganisms into a body cavity.

A person of ordinary skill in the art would have been motivated to formulate a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, and glutaraldehyde because of the reasonable expectancy of success in inhibiting the intrusion of microorganisms into a body cavity.

Claim(s) 51 is rejected under 35 U.S.C. 103(a) as being obvious over Beckman et al. (US Patent Application 2002/0015697 A1) as applied to claims 24-32, 34-36, 38, 41-50, 52-53 in view of Stoner (US Patent 4,925,033).

The instant claims are directed to a method of inhibiting the intrusion of microorganisms into a body cavity of a mammal comprising applying into the body cavity a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, spermicide, and glutaraldehyde.

Beckman et al. teach as disclosed above, however, do not teach spermicide in the composition.

Stoner teaches that a microbicidal cleanser composition to be used during sexual contact (abstract) so as to prevent the transmission of sexually transmitted diseases. This composition may also be in the form of contraceptives, such as coating fluids (foams, creams, jellies) to be used on the genitals. A well-known composition of the above type is nonoxynol-9, a spermicidal compound that also acts as an anti-microbial agent (col. 1, lines 19-58).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to combine the antimicrobial composition disclosed by Beckman et al. with the spermicidal composition disclosed by Stoner.

A person of ordinary skill in the art would have been motivated to combine the antimicrobial composition disclosed by Beckman et al. with the spermicidal composition disclosed by Stoner because: (1) both compositions are disclosed to possess

antimicrobial properties; (2) both compositions are to be used on the genitals, such as the vaginal cavity; (3) Stoner discloses that antimicrobial compositions comprising spermicides are used to prevent sexually transmitted diseases; and (4) Stoner discloses nonoxynol-9, a well-known spermicidal compound that also acts as an anti-microbial agent. Therefore, the skilled artisan would have had a reasonable expectation of success in preventing STDs by administering a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, spermicide, and glutaraldehyde.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Response to Arguments

Applicant argues that Beckman requires the use of a transition metal for reducing microbial populations and then argues that transition metals are known to potentially enhance bacterial growth and worsen bacterial infections. Applicant also recites "consisting essentially of" language so as to preclude the inclusion of transition metals.

This is not persuasive because Beckman teaches that under certain circumstances, transition metals can be toxic to bacterial cells via the formation of the hydroxyl radical (section 0037). In fact, the invention as taught by Beckman overcomes

the limitations of the art, as noted above by Applicant, by providing methods in which the process of reducing microbial populations can optionally be performed in surprisingly short periods of time. In addition, the present invention optionally employs low doses of free iron in the order of 100 micromolar or less (section 0040). With regard to the transitional phrase "consisting essentially of," Examiner submits that Applicant has not established how or why the inclusion of transitional metals would materially affect the novel characteristics of the claimed invention. Applicant's reasoning of not using a transition metal being safer contradicts the teachings of Beckman, therefore the toxic effect argument is irrelevant.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

Applicant argues that the three ingredients of the composition do not appear in one embodiment of Beckman, in fact, the reference teaches away from the three components being in one embodiment. Applicant argues that water is only mentioned in an oral rinse and not a gel, which are incompatible with each other. Moreover, the use of polyvinylpyrrolidone is limited to use in wound dressings, which is not an oral rinse, and thus does not contain water. Thus, Beckman does not disclose a gel and water together forming a hydrogel.

This is not persuasive because, as admitted by the Applicant, Beckman teaches, in general, that the compositions disclosed therein can be in the form of a gel. One of ordinary skill in the art knows that a hydrogel is a well known type of gel, which contains water. This is a typical genus species type of relationship that is obvious over one another. In fact, the gel matrix is known to consist of a liquid medium, with water being a more popular choice. Since Beckman provides other compositions that contain water such as in the form of an oral rinse, there can be no teaching away from the combination of water and the compositions contemplated by Beckman. It is this combination of water and a gel that forms a hydrogel. Finally, Beckman teaches that the composition can be applied to many different substrates or used in various capacities, such as wound dressings.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S Chong/
Primary Examiner, Art Unit 1617

YSC